



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,704	09/21/2006	Jun Hirabayashi	20846/0205032-US0	9747
7278	7590	08/18/2009		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER	
			SKOWRONEK, KARL HEINZ R	
			ART UNIT	PAPER NUMBER
			1631	
			MAIL DATE	DELIVERY MODE
			08/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/596,704

Applicant(s)

HIRABAYASHI ET AL.

Examiner

KARLHEINZ R. SKOWRONEK

Art Unit

1631

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date 2/20/09/25/07/11/10/7
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group II in the reply filed on 09 June 2009 is acknowledged. The traversal is on the ground(s) that share the same inventive feature, the immobilization of proteins. This is not found persuasive because the technical feature upon which applicant relies is not special and was known in the prior art. IDS submission of 2 February 2007 reference CD shows this technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Claim Status

Claims 1-11 are pending.

Claims 1-5 are withdrawn as being directed to a non-elected invention.

Claims 6-11 have been examined.

Claims 6-11 are rejected.

Priority

This application was filed on 21 September 2006 and is the 35 USC 371 National Stage Application of PCT/JP04/09600, filed on 30 June 2004 and claims priority to Japanese Application No. 2003-430615, filed on 25 December 2003.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed received.

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on 2 February 2007, 25 September 2007, and 1 November 2007 are in compliance with the provisions of 37

CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Drawings

The drawings were received on 22 June 2006. These drawings are accepted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

As set forth below, claims 9-11 invoke 35 USC 112, Sixth Paragraph. The MPEP2181 (II) states, "If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112." In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc). In the instant case, the specification does not provide an adequate disclosure showing the structure, material or acts for these "means-plus-function" limitations, for reasons as set forth below. Therefore, applicant fails to particularly point out and distinctly claim the invention as required by the second paragraph of 35 USC 112, and one skilled in the art would not know what are meant by these "means-plus-function" limitations, and the metes and bounds of the claimed invention are thus unclear.

First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claim 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 9-11 are directed to a system for analyzing sugar chain structure. First, claims 9-11 recite limitations using the phrase "means for". Second, in claims 9-11 the recited limitation modifies the phrase "means for" with functional language. For example, line 5 recites, "a detection means which...detects". Finally, the "means for" phrases of claims 9-11 are not modified by sufficient structure, material, or act for achieving the functions of claims 9-11. Based on the previous three conditions in claims 9-11, the limitations of claims 9-11 are considered to invoke 35 USC 112, Sixth paragraph as set forth in MPEP 2181.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language." In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc).

In the instant case, the specification fails to set forth an adequate disclosure of what is meant by "a storage means", "a display means", "means for taking a data combination" and "a detection means" as recited in claim 9.

Claims 9-11 are indefinite because the metes and bounds of the claimed means have not been pointed out particularly in the disclosure. The disclosure fails to show, for example, a "storage means". At p.21, lines 4-15 and referring to figure 4, the specification provides the example of a composition of a computer system comprising three means for storage. The storage means appear to be distinct entities. However, the description fails to describe how one of ordinary skill would identify the appropriate structures each storage means. The description does not set for the material or structure for the means as recited in claims 9-11. Thus, one of skill in the art would be reasonably doubt that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (WO 02/083918) in view of Nilsson (Analytical Chemistry, Volume 75, Issue 15, p.348-353, 01 August 2003) and in view of Joos et al. (Current Opinion in Chemical Biology, 2001, Vol. 6, p.76-80).

Claim 6 is direct to a method of analyzing oligosaccharides in which a fluorescently labeled oligosaccharide sample contacts a solid support comprising a plurality of proteins and detecting the pattern of protein-oligosaccharide binding without washing. In the embodiment of claim 7, the excitation light is an evanescent wave. In the embodiment of claim 8, the protein is a lectin.

Wang shows method of detecting the binding of an agent to a microarray (p. 28). Wang shows, as in the embodiment of claim 8, lectins or antibodies are immobilized on

the microarray (p. 28). Wang defines agents to be glycomers or oligosaccharides (p. 22 and p. 23). Wang shows the determination of binding is made by detecting fluorescence (p. 29).

Wang et al. does not explicitly show determining a pattern of oligosaccharide binding to lectin to analyze structure or detecting without washing.

Nilsson provides a discussion of lectins and their binding of oligosaccharides. Nilsson shows lectins are proteins that recognize and bind to specific carbohydrate structural epitopes (p. 349, col. 2). Nilsson shows that lectins recognize different sugar structures, make lectins invaluable biochemical tools (p.350, col. 1). Nilsson shows using microarray techniques binding partners can be made by either linking the protein or the carbohydrate to a solid surface (p. 351, col. 1). Nilson shows that the pattern of lectin binding to oligosaccharides can be determined using microarrays (p. 351, col. 1). Thus, the structural organization of the saccharide constituents is determined.

Joos et al. shows that the sensitivity of protein arrays can be increased by excitation of fluorophores with evanescent waves (p. 78, col. 1). The use of evanescent waves also allows to perform microarray binding detection without washing steps (p. 78, col. 1). Joos et al. shows that (p. 78, col. 1).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Wang for the detection of oligo saccharide agents using lectins immobilized on a substrate to analyze oligosaccharide structure as suggested by Nilsson because Nilsson shows the ability of lectins to recognize different sugar structures makes lectins in valuable biochemical tools. It would have been further

obvious to one of ordinary skill in the art at the time of invention to modify the method of Wang for the detection of oligo saccharide agents using lectins immobilized on a substrate to analyze oligosaccharide structure as suggested by Nilsson with detection using evanescent waves of Joos et al. because Joos et al. shows evanescent waves have the advantage of providing signals that are a hundred times higher than conventional excitation.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of Nilsson in view of Joos et al. as applied to claims 6-8 above, and further in view of and Shalon et al. (Genome Res., Vol. 6, p. 639-645, 1996) in view of Pawlak et al. (Proteomics 2002, 2, 383-393).

Claim 9 is directed to a system comprising a storage means; a detection means; a calculating means, and a displaying means that implements a method of analyzing sugar chains.

Wang in view of Nilsson in view of Joos et al. as applied to claims 6-8 above shows a method of analyzing sugar chains using evanescent waves.

Wang in view of Nilsson in view of Joos et al. does not explicitly show a system Shalon et al. shows a microarray system comprising a storage means; a detection means; a calculating means, and a displaying means (p. 644, col. 2).

Pawlak et al. shows a microarray system adapted with a specialized detection means to detect signals from microarray substrates that rely on evanescent waves (p. 385, col. 1). Pawlak et al. shows that the differences between the evanescent wave and

conventional excitation, such as that performed in Shalon et al., is approximately an 80-fold increase in signal to noise (figure 1). Pawlak et al. shows the evanescent wave excitation allows one to omit washing steps during microarray hybridization which is especially beneficial for weak affinity reactions as a dissociation of weak complexes during washing can be avoided (p393, col. 1).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Wang in view of Nilsson in view of Joos et al. as applied to claims 6-8 above to perform the method with the system of Shalon et al. because all the claimed elements were known, in the prior art, and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention. It would have been further obvious to modify the detection means of Shalon et al. with the detection means of Pawlak et al. because Pawlak et al. shows the evanescent wave excitation allows one to omit washing steps during micro array hybridization which is especially beneficial for weak affinity reactions as a dissociation of weak complexes during washing can be avoided.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 11, and 12 of copending Application No. 10/596692. Although the conflicting claims are not identical, they are not patentably distinct from each other. The method as in claim 6 of the instant application is directed to a method in which a fluorescent oligosaccharide is contacted with a substrate comprising immobilized protein and measuring the interaction. Similarly, in claim 1 of copending Application No. 10/596,692, a method is claimed in which a fluorescent oligosaccharide is contacted with a substrate comprising immobilized protein and measuring the interaction.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 9-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 11/917,921. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 9-11 of the instant application are

directed to an apparatus or system comprising a storage means, detection means, calculation means, and a display means in which evanescent waves are used to excite fluorophores and lectins are immobilized on a substrate. Similarly claims 1-9 of copending Application No. 11/917,921 are also directed to an apparatus comprising storage means, a measuring or detecting means, and a calculation means. Although claims 1-9 of copending Application No. 11/917,921 do not show a display means, it would be obvious to one of ordinary skill in the art to modify the apparatus of copending Application No. 11/917,921 to include a display means. Such a modification would advantageously provide results of the apparatus function to the user.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARLHEINZ R SKOWRONEK/
Examiner, Art Unit 1631

18 August 2009